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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,956	06/15/2000	Yukie Tokiwa	ASA-888	9224

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT PAPER NUMBER

1743

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/593,956

Applicant(s)

TOKIWA ET AL.

Examiner

Samuel P Siefke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **1-11** are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (USPN 5,532,941).

Lin discloses an inter-laboratory performance monitoring system. Measurements are made on a sample (glucose, cholesterol, total protein, etc.). Sets of known control (calibration) samples are taken from the lot obtained from a central standard agency and then processed on the instrument and a set of control data is obtained. The control data is stored and then processed with statistical techniques to determine performance ratings for the laboratory (averaging, creating standard deviations) (col. 1, lines 30-63). The feature of this invention that the instruments produce control data at widely geographically dispersed locations and the control data readings are input to the system from the areas to a central station. The central station (40) is made up of a number of modules (measurement channels), including communication interface, data storage module for storing data, along with processors for processing the information and data

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and displaying the calibration information (fig. 2). A target module operates on the collected data at predetermined intervals (col. 3, lines 6-39). Certain instruments which are performing at a predetermined level of operation are determined with statistical means (col. 6, lines 11-28).

Claims **1-11** are rejected under 35 U.S.C. 102(e) as being anticipated by EP 0871034 A2.

EP '034 discloses an automatic analyzer and support system, which comprises a plurality of analytical units (measurement chambers) to which analysis items are allocated. When execution of calibration or accuracy management occurs, a display block relating to an occurrence cause among a plurality of display blocks on a state inspection screen flickers. When a button corresponding to the flickering display block is instructed, the related analysis item name and analytical unit name are displayed in the display area and calibration or accuracy management is executed (abstract; col. 6, lines 9-55; col. 21, line 23-col. 22, line 22). A second quality control information contains an average value and a standard deviation value (col. 9 line 50-col. 10 line 11). The data processor sets each of preselected allowable values with respect to the calibration information along with judging means for allowing or failing the calibration step (col. 14, line 28-col. 15, line 33). The processor displays that the standard deviation is off and correction in calibration is needed (col. 19, line 8-col. 20, line 48).

Response to Arguments

Applicant's arguments filed 9/30/03 have been fully considered but they are not persuasive. The Applicant argues, "that Lin does not show calibration data." Lin uses known control samples for calibrating and monitoring the quality of the measurement channels. A control is a way to calibrate and make sure that the instrument or apparatus is functioning properly and accurately. Without known control samples (calibration sample) an apparatus would render itself unusable because each sample would not be able to be compared to a baseline value. Each prior art uses these known control samples as calibration and quality assurance.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 703-306-0093. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9311 for regular communications and 703-872-9310 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Sam P. Siefke



November 24, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

